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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,697	04/11/2005	Mario Pablo Estrada Garcia	294-194 PCT/US/RCE	6631
23869	7590	07/22/2009		
HOFFMANN & BARON, LLP 6900 JERICO TURNPIKE SYOSSET, NY 11791			EXAMINER WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	
			MAIL DATE	DELIVERY MODE
			07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,697	Applicant(s) ESTRADA GARCIA ET AL.	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-28 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 16-28 and 31 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed May 8, 2009, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

The restriction requirement of record has been withdrawn based upon the newly entered amendments and the claims have been rejoined on the record.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 4, 2008, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Hipkind et al (US 5773441), cited on previously enclosed PTO-892 Form.

Claims are drawn to a formulation with sequence His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂. Also claims are drawn to a method for stimulating resistance to diseases in fish and crustaceans comprising administering to these animals an effective amount of GHRP-6 comprising SEQ ID NO: 1, which is His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂.

Hipkind et al teach GHRP-6 comprising His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂. Note col. 2, lines 29 and 35. Furthermore, artificial manipulation of growth hormone levels have been demonstrated to have significant therapeutic utility for disease states in humans. Also increase in lean muscle mass has been observed as well in animals, thus this makes animals stronger by increasing their protein to fat ratio. Note col. 1, lines 10-25. The GHRP-6 has been used in animal husbandry as an effective agent. The peptides are orally bioavailable, note col. 2, line 48. The reference teaches broadly several compounds which are useful for all types of animals including fish, note col. 3, line 63. Also, the composition can be injected and given orally.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the formulation and method for stimulating disease resistance in fish and crustaceans because the cited reference clearly teaches that the GHRP-6 having the identical sequence is useful for animal husbandry agents and a variety of animals are disclosed to be treatable with a variety of compounds for affecting growth hormone levels in for example fish. Clearly Hipskind et al recognized the usage of GHRP-6 as claimed herein and to treat fish and crustaceans is clearly an obvious modification of the cited prior art. The reference teaches that fish are treatable and also recognizes the identical agent to be an effective animal husbandry agent. To orally, inject, or immerse an animal such as a fish or crustacean with this agent as claimed is well within the purview of an ordinary artisan.

Also to vary the effective amounts is well within a manner of routine experimentation and one of skill would have expected successful results. To vary the protocol of treatment over several days is also well within the purview of an artisan, as is the encapsulation of feed for administering to fish and crustaceans. Also to select from tilapia or salmon species and the varied crustaceans of *Litopenaeus* and *Penaeus* is a matter of routine experimentation and one of skill would have expected successful results for treating all of these type of animals. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the newly cited prior art rejection.

Response to Arguments

Applicant's arguments filed May 8, 2009, have been fully considered but they are not persuasive. The argument that treating disease in fish is not disclosed is noted, however, at col. 43, lines 44-45, it is disclosed that immune-suppressed subjects are treatable and at col. 42, line 64, GHRP-6 is also used in combination for treatment methods. The reference clearly teaches that GHRP-6 has a prophylactic effect on disease. Treatment of fish is also disclosed as discussed above. Therefore, Hipkind clearly teach, or at least suggest, that GHRP-6 has disease treating effect on animals including fish. To treat other marine organisms such as crustaceans would have been prima facie obvious. The argument that the reference teaches away from GHRP-6 is not persuasive because at col. 42, line 64, GHRP-6 is disclosed to be useful in the whole invention of Hipkind. To administer the composition of Hipkind via injection or orally in feed, is clearly a matter of judicious selection by one of ordinary skill in the art and the reference teaches both modes of administration of the disclosed composition which can include GHRP-6. Also since fish and crustaceans are water animals immersion would have been typical for orally administering the GHRP-6 and expected to provide successful results. The reference clearly suggests treating fish and other animals with GHRP-6, note col. 42, line 64. Hence, the rejection is sustained for these reasons and those of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Deborah K. Ware
Art Unit 1651

/David M. Naff/
Primary Examiner, Art Unit 1657